PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Marian DEVONEC

Prior Group Art Unit: 3763

Divisional of Application No.: 08/765,199

Prior Examiner: C. Rodriguez

Filed: April 5, 2001

Docket No.: 039179.01

For: THERAPEUTIC DEVICE FOR THE SELECTIVE CYTOREDUCTION TREATMENT OF AN OBSTRUCTION IN A NATURAL LUMEN OR PASSAGE OF THE HUMAN OR ANIMAL BODY

PRELIMINARY AMENDMENT

Director of the U.S. Patent and Trademark Office
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-identified patent application as follows:

IN THE SPECIFICATION:

Page 1, line 1, please insert the following title:

THERAPEUTIC DEVICE FOR THE SELECTIVE CYTOREDUCTION TREATMENT OF AN OBSTRUCTION IN A NATURAL LUMEN OR PASSAGE OF THE HUMAN OR ANIMAL BODY

Page 1, lines 5-6, please insert the following subheadings:

BACKGROUND OF THE INVENTION

1. Field of the Invention

Page 1, line 33, please insert the following subheading:

2. Description of Related Art

Page 2, line 19, please insert the following subheading:

SUMMARY OF THE INVENTION

Page 8, line 1, please insert the following subheading:

BRIEF DESCRIPTION OF THE DRAWINGS

Page 8, lines 9-16, delete current paragraph and insert therefor:

- Figures 2 and 3 each represents a therapeutic device according to the present invention, in a frontal view, with its upstream end at the top and its downstream end at the bottom; Figure 2 is in its configuration before implantation, that is to say ready for use, and Figure 3 is in its configuration after implantation and activation, that is to say in the urethra, although the urethra is not represented in Figure 3;

Page 9, lines 2-7, delete current paragraph and insert therefor:

- Figures 10 and 11 represent, in axial section, another embodiment of a therapeutic device according to the present invention, before implantation, and, respectively, after implantation and activation in the urethra, the urethra not being represented;

Page 10, line 7, please insert the following subheading:

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Page 19, lines 35-38, delete current paragraph and insert therefor:

- the flexible connection sleeve 16 between the tubular elements 3 and 14 can be perforated, in a manner distributed about its perimeter, especially by longitudinal slots or windows;

IN THE CLAIMS:

Please cancel claims 1-20 without prejudice to or disclaimer of the subject matter contained therein.

Please add new claims 21-124 as follows:

--21. A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in the prostatic portion of a male urethra, comprising:

a non-biodegradable element that is designed to be placed and retained in a prostatic portion of the male urethra to maintain a channel, said element being sufficiently flexible to conform to the urethra, but sufficiently rigid to maintain the channel for urine flow in the prostatic portion, the channel providing for passage of urine from upstream of the obstruction to downstream of the obstruction; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the prostatic portion of the male urethra, when said element is retained in the prostatic portion of the male urethra,

wherein said device further comprises a withdrawal thread and is non-traumatically removable from the male urethra by said withdrawal thread following treatment of the obstruction.--

--22. The device of claim 21, wherein said device is configured to be self-stabilizing.--

--23. The device of claim 21, wherein said element is of cylindrical shape.--

--24. The device of claim 21, wherein said cytoreductive agent is selectively reductive to cells of the obstruction.--

--25. The device of claim 21, wherein said cytoreductive agent is cytotoxic to prostatic cells.--

--26. The device of claim 21, wherein said cytoreductive agent is reductive to urethral mucosal cells.--

--27. The device of claim 21, wherein said cytoreductive agent extends around a perimeter of said element.--

--28. The device of claim 21, wherein said cytoreductive agent is supported by said element.--

--29. The device of claim 21, wherein said cytoreductive agent is distinct from said element and covers said element.--

--30. The device of claim 21, wherein said cytoreductive agent is located on or in a sleeve, which is positioned along said non-biodegradable element.--

--31. The device of claim 21, wherein said cytoreductive agent is incorporated in said element.--

--32. The device of claim 21, wherein said element comprises (*i*) a core made of a biocompatible material and (*ii*) a biologically active zone, and wherein in the biologically active zone of said element, said biocompatible material of said core incorporates said cytoreductive agent, at least on a surface of said biologically active zone.--

--33. The device of claim 32, wherein said core made of biocompatible material is made of silicone rubber.--

--34. The device of claim 21, wherein said element comprises an internal core made of a biocompatible material, and said cytoreductive agent is located on or in a biologically compatible substrate covering at least a portion of said internal core.--

--35. The device of claim 34, wherein said internal core is made of silicone rubber.--

--36. The device of claim 34, wherein said cytoreductive agent and said internal core are off-centered in relation to one another.--

--37. The device of claim 34,

wherein said element has an outer surface,

wherein said substrate is radially expandable, and

wherein said substrate has an outer surface that is inscribed within said outer surface of said element, and, in the expanded position, emerges from said outer surface of said element.--

--38. The device of claim 34, wherein said substrate is hydrophilic and expandable under the effect of biological fluids present or circulating in the obstructed prostatic portion of the male urethra.--

--39. The device of claim 34, further comprising a sheath made of a synthetic foam between said cytoreductive agent and said internal core.--

--40. The device of claim 34, wherein said substrate comprises a plurality of radial channels.--

--41. The device of claim 21, wherein said device comprises a bacteriostatic agent.--

--42. The device of claim 21, comprising means for checking the correct positioning of said device.--

--43. The device of claim 21, comprising an agent which is opaque vis-a-vis X-rays.--

--44. The device of claim 21, wherein said cytoreductive agent is not hydrosoluble.--

--45. The device of claim 21, wherein said cytoreductive agent comprises at least one medicament selected from the group consisting of antimitotic agents, cytolytic agents, enzymes, hormones, antienzymes, and metal salts.--

--46. The device of claim 21, wherein said element comprises a bottom end and a top end, and wherein said cytoreductive agent is positioned between said bottom end and said top end of said element.--

--47. The device of claim 46, wherein said top end of said element is blind, and includes at least one perforation in order to ensure the passage of urine.--

--48. The device of claim 21, wherein said cytoreductive agent is cytotoxic to urethral mucosal cells.--

--49. A method of treating an obstruction of the prostatic portion of the male urethra, comprising inserting said device of claim 21 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine from the bladder.--

--50. The method of claim 49, wherein said cytoreductive agent causes a reduction in the obstruction.--

--51. The method of claim 50, wherein said cytoreductive agent causes the reduction in the obstruction when in direct contact with the obstruction.--

--52. The method of claim 51, wherein said cytoreductive agent gradually ceases to cause the reduction in the obstruction as direct contact of said device with the obstruction ceases.--

--53. The method of claim 50, further comprising removing said device once sufficient reduction has occurred that normal urine flow can be achieved in the absence of said device.--

--54. The method of claim 49, wherein the obstruction is a tumoral obstruction.--

--55. The method of claim 54, wherein said cytoreductive agent erodes the tumoral obstruction.--

--56. The method of claim 49, further comprising temporarily maintaining said device in the male urethra and then removing said device from the male urethra.--

--57. A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen,

wherein said device further comprises a withdrawal thread and is non-traumatically removable from the natural lumen by said withdrawal thread following treatment of the obstruction.--

--58. The device of claim 57, wherein said device is configured to be self-stabilizing.--

--59. The device of claim 57, wherein said element is of cylindrical shape.--

--60. The device of claim 57, wherein said cytoreductive agent is selectively reductive to cells of the obstruction.--

--61. The device of claim 57, wherein said cytoreductive agent is cytotoxic to cells of a wall of said lumen.--

--62. The device of claim 57, wherein said cytoreductive agent is reductive to urethral mucosal cells.--

--63. The device of claim 57, wherein said cytoreductive agent extends around a perimeter of said element.--

--64. The device of claim 57, wherein said cytoreductive agent is supported by said element.--

--65. The device of claim 57, wherein said cytoreductive agent is distinct from said element and covers at least a portion of said element.--

--66. The device of claim 57, wherein said cytoreductive agent is located on or in a sleeve, which is positioned along said non-biodegradable element.--

--67. The device of claim 57, wherein said cytoreductive agent is incorporated in said element.--

--68. The device of claim 57, wherein said element comprises (*i*) a core made of a biocompatible material, and (*ii*) a biologically active zone, and wherein in the biologically active zone of said element, said biocompatible material of the core incorporates said cytoreductive agent.--

--69. The device of claim 68, wherein said core made of biocompatible material is made of silicone rubber.--

--70. The device of claim 57, wherein said element comprises an internal core made of a biocompatible material, and said cytoreductive agent is located on or in a biologically compatible substrate covering at least a portion of said internal core.--

--71. The device of claim 70, wherein said internal core is made of silicone rubber.--

--72. The device of claim 70, wherein said cytoreductive agent and said internal core are off-centered in relation to one another.--

--73. The device of claim 70,

wherein said element has an outer surface,

wherein said substrate is radially expandable, and

wherein said substrate has an outer surface that is inscribed within said outer surface of said element, and, in the expanded position, emerges from said outer surface of said first element.--

--74. The device of claim 70, wherein said substrate is hydrophilic and expandable under the effect of biological fluids present or circulating in the obstructed natural lumen.--

--75. The device of claim 70, comprising a sheath made of a synthetic foam between said cytoreductive agent and said internal core.--

--76. The device of claim 70, wherein said substrate comprises a plurality of radial channels.--

--77. The device of claim 57, wherein said device comprises a bacteriostatic agent.--

--78. The device of claim 57, comprising means for checking the correct positioning of said device.--

--79. The device of claim 57, comprising an agent which is opaque vis-a-vis X-rays.--

--80. The device of claim 57, wherein said cytoreductive agent is not hydrosoluble.--

--81. The device of claim 57, wherein said cytoreductive agent comprises at least one medicament selected from the group consisting of antimitotic agents, cytolytic agents, enzymes, hormones, antienzymes, and metal salts.--

--82. The device of claim 57, wherein said element comprises a bottom end and a top end and wherein said cytoreductive agent is positioned between said bottom end and said top end of said element.--

--83. The device of claim 82, wherein said cytoreductive agent is positioned between 10 and 15 mm from both said bottom end and said top end of said element.--

--84. The device of claim 82, wherein said top end of said element is blind, and includes at least one perforation in order to ensure the passage of the fluid.--

--85. The device of claim 57, further comprising an other element attached to said non-biodegradable element by a flexible connection.--

--86. The device of claim 85, wherein said other element does not comprise or support a cytoreductive agent.--

--87. The device of claim 85, wherein said other element comprises a core made of a biocompatible but non-biodegradable material.--

--88. The device of claim 87, wherein said biocompatible but non-biodegradable material of said other element is silicone rubber.--

--89. The device of claim 85, wherein at least a portion of said other element is radially expandable.--

--90. A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 57 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing normal passage of the fluid.--

--91. The method of claim 90, wherein said cytoreductive agent causes a reduction in the obstruction.--

--92. The method of claim 91, wherein said cytoreductive agent causes the reduction in the obstruction when in direct contact with the obstruction.--

--93. The method of claim 92, wherein said cytoreductive agent gradually ceases to cause the reduction in the obstruction as direct contact of said device with the obstruction ceases.--

--94. The method of claim 91, further comprising removing said device once sufficient reduction has occurred that the natural lumen can function normally in the absence of said device.--

--95. The method of claim 91, wherein the obstruction is a tumoral obstruction.--

--96. The method of claim 95, wherein said cytoreductive agent erodes the tumoral obstruction.--

--97. The method of claim 90, further comprising temporarily maintaining said device in the natural lumen and then removing said device from the natural lumen.--

--98. A therapeutic device intended for substantially fully intracorporeal insertion for reduction of a pre-existing obstruction in a natural lumen for flow of a fluid, the lumen being obstructed by the effect of a local cell proliferation, said device comprising:

a non-biodegradable element adapted to be placed and retained in the natural lumen to maintain a channel, and sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the natural lumen, the channel providing for passage of the fluid from upstream to downstream of the obstruction with respect to the natural fluid flow; and

a sleeve which is supported by said element and which is positioned along said element so as to come into contact with the obstruction when said element is retained in the

natural lumen, wherein said sleeve supports or comprises a cytoreductive agent that causes reduction of the pre-existing obstruction.--

--99. The device of claim 98, wherein said cytoreductive agent is selectively reductive to cells of the obstruction.--

--100. The device of claim 98, wherein said device is an intraurethral therapeutic device and wherein the fluid is urine, which is allowed to pass from upstream to downstream of the obstruction.--

--101. A method of treating a pre-existing obstruction of a natural lumen, comprising inserting said device of claim 98 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing normal passage of the fluid.--

--102. A method for treating a pre-existing obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 100 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.--

--103. The method of claim 101, wherein the obstruction is a tumoral obstruction.--

--104. The method of claim 103, wherein said agent erodes the obstruction.--

--105. A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen, wherein said cytoreductive agent is non-selectively cytotoxic.--

--106. The device of claim 105, wherein said natural lumen is the prostatic portion of a male urethra.--

--107. A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 105 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.--

--108. A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 106 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.--

--109. A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen,

wherein said reductive effect is through direct contact of said device with cells of the obstruction, the reductive effect ceasing when direct contact ceases.--

--110. The device of claim 109, wherein said natural lumen is the prostatic portion of a male urethra.--

--111. A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 109 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.--

--112. A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 110 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.--

--113. A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable tubular element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along a length of said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen,

wherein said tubular element has a continuous surface both around said element and along said length of said element.--

--114. The device of claim 113, wherein said natural lumen is the prostatic portion of a male urethra.--

--115. A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 113 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.--

--116. A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 114 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.--

--117. A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen,

wherein said non-biodegradable element is non-expandable.--

--118. The device of claim 117, wherein said natural lumen is the prostatic portion of the male urethra.--

--119. A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 117 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.--

--120. A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 118 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.--

--121. A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along a length of said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen;

wherein said cytoreductive agent has a continuous surface both around said element and along said length of said element.--

--122. The device of claim 121, wherein said natural lumen is the prostatic portion of the male urethra.--

--123. A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 121 into the obstructed natural lumen so that said element is positioned

in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.--

--124. A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 122 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.--

REMARKS

Claims 21-124 are pending. Claims 1-20 are canceled and claims 21-124 are added herein. The attached Appendix includes marked-up copies of each rewritten paragraph (37 C.F.R. §1.21(b)(iii)).

Early and favorable consideration on the merits is respectfully requested.

Respectfully submitted,

William P. Berridge
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WPB:MLM/jca

Attachment:
Appendix

Date: April 5, 2001

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION
Please grant any extension necessary for entry;
Charge any fee due to our Deposit Account No. 15-0461

APPENDIX

Changes to Specification:

Page 1, line 1, the title is added.

Page 1, lines 5-6, the subheadings "BACKGROUND OF THE INVENTION" and "1. Field of the Invention" are added.

Page 1, line 33, the subheading "2. Description of Related Art" is added.

Page 2, line 19, the subheading "SUMMARY OF THE INVENTION" is added.

Page 8, line 1, the subheading "BRIEF DESCRIPTION OF THE DRAWINGS" is added.

Page 10, line 7, the subheading "DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS" is added.

The following are marked-up versions of the amended paragraphs:

Page 8, lines 9-16:

- Figures 2 and 3 each represents a therapeutic device according to the present invention, in a frontal view, with its upstream end at the top and its downstream end at the bottom,; Figure 2 is ~~respectively~~ in its configuration before implantation, that is to say ready for use, and Figure 3 is in its configuration after implantation and activation, that is to say in the urethra, although the urethra~~latter~~ is not represented in Figure 3;

Page 9, lines 2-7:

- Figures 10 and 11 represent, in axial section, another embodiment of a therapeutic device according to the present invention, before implantation, and, respectively, after implantation and activation in the urethra, the urethra~~latter~~ not being represented;

Page 19, lines 35-38:

- the flexible connection sleeve 16 between the tubular elements 3 and 14 can be perforated~~openworked~~, in a manner distributed about its perimeter, especially by longitudinal slots or windows;

Changes to Claims:

Claims 1-20 are canceled.

Claims 21-124 are added.